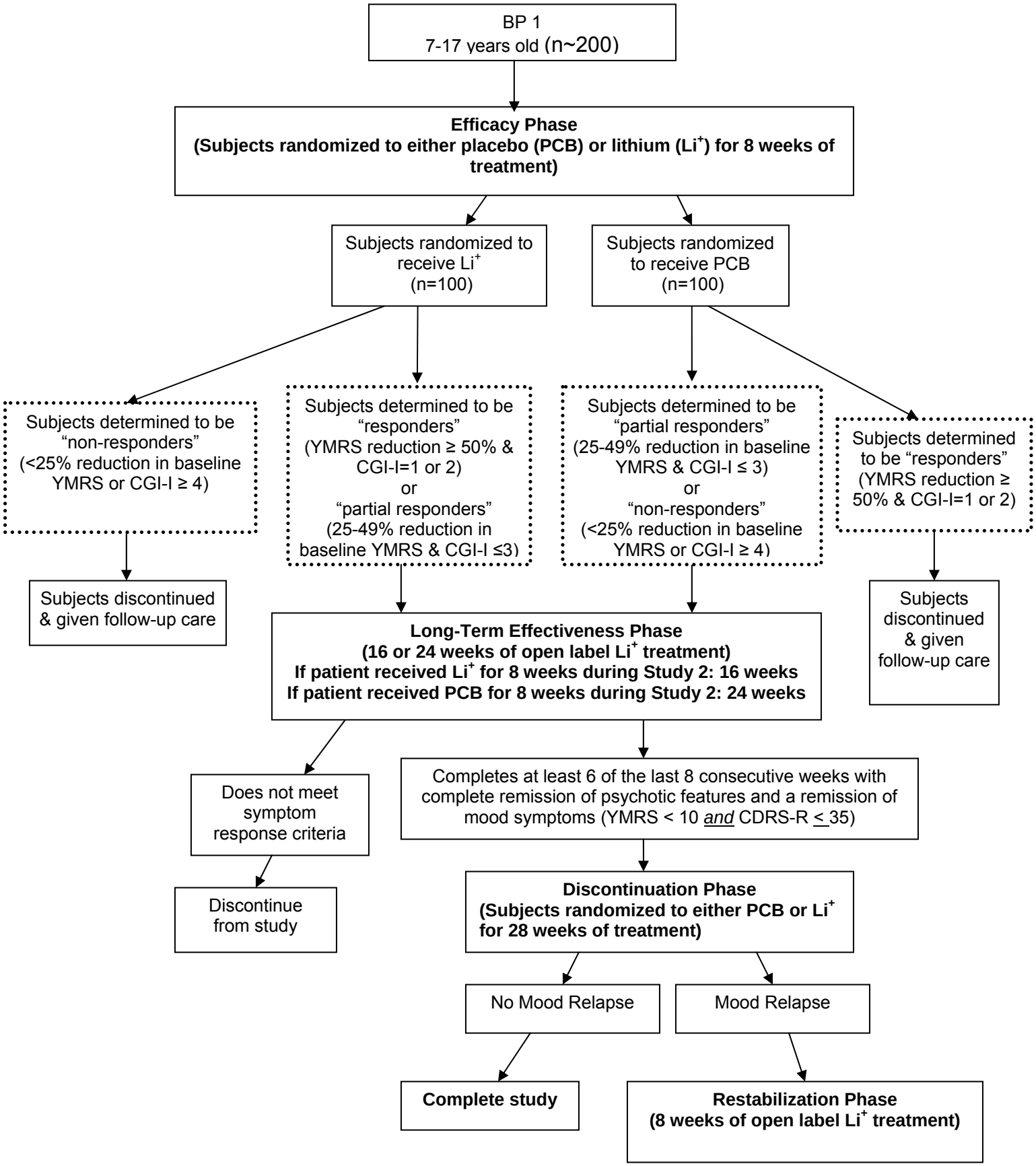
BP 1
7-17 years old (n~200)
Efficacy Phase
(Subjects randomized to either placebo (PCB) or lithium (Li+) for 8 weeks of treatment)
Subjects randomized to receive Li+ (n=100)
Subjects randomized to receive PCB (n=100)
Subjects determined to be "non-responders" (<25% reduction in baseline YMRS or CGI-I ≥ 4)
Subjects determined to be "responders" (YMRS reduction ≥ 50% & CGI-I=1 or 2) or "partial responders" (25-49% reduction in baseline YMRS & CGI-I ≤3)
Subjects determined to be "partial responders" (25-49% reduction in baseline YMRS & CGI-I ≤ 3) or "non-responders" (<25% reduction in baseline YMRS or CGI-I ≥ 4)
Subjects determined to be "responders" (YMRS reduction ≥ 50% & CGI-I=1 or 2)
Subjects discontinued & given follow-up care
Long-Term Effectiveness Phase
(16 or 24 weeks of open label Li+ treatment)
If patient received Li+ for 8 weeks during Study 2: 16 weeks
If patient received PCB for 8 weeks during Study 2: 24 weeks
Subjects discontinued & given follow-up care
Does not meet symptom response criteria
Completes at least 6 of the last 8 consecutive weeks with complete remission of psychotic features and a remission of mood symptoms (YMRS < 10 and CDRS-R ≤ 35)
Discontinue from study
Discontinuation Phase
(Subjects randomized to either PCB or Li+ for 28 weeks of treatment)
No Mood Relapse
Mood Relapse
Complete study
Restabilization Phase
(8 weeks of open label Li+ treatment)